(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 21 April 2005 (21.04.2005)

PCT

(10) International Publication Number WO 2005/035000 A1

(51) International Patent Classification⁷: 9/08, 31/4458

A61K 47/12,

(21) International Application Number:

PCT/US2004/033268

- (22) International Filing Date: 7 October 2004 (07.10.2004)
- (25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data: 60/509,704

8 October 2003 (08.10.2003) US

- (71) Applicant (for all designated States except US): MALLINCKRODT INC. [US/US]; 675 McDonnell Boulevard, P.O. Box 5840, St. Louis, MO 63134 (US).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): HERMAN, Clifford, J. [US/US]; 216 Portland Terrace, St. Louis, MO 63119 (US).
- (74) Agents: REBMAN, Christine, M. et al.; Mallinckrodt Inc., 675 McDonnell Boulevard, P.O. Box 5840, St. Louis, MO 63134 (US).

- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHYLPHENIDATE SOLUTION AND ASSOCIATED METHODS OF ADMINISTRATION AND PRODUCTION

(57) Abstract: A methylphenidate solution and associated methods of administration and production, which includes methylphenidate and at least one organic acid dissolved in a solvent system, where the solvent system includes at least one non-aqueous solvent. The solvent system may include water. The non-aqueous solvent can include, but is not limited to polyols and glycols and associated mixtures thereof. Pharmaceutical additives such as flavorings, colorants, buffers, preservatives and mixtures thereof may be optionally added to the methylphenidate solution.